



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-------------------------------|-------------|----------------------|---------------------|------------------|
| 10/781,069 | 02/18/2004 | Armin Meinzer | 100-8388C | 1856 |
| 1095 | 7590 | 05/03/2006 | EXAMINER | |
| CHANNAVAJJALA, LAKSHMI SARADA | | | | |
| ART UNIT | | PAPER NUMBER | | |
| | | 1615 | | |

DATE MAILED: 05/03/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|--------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/781,069 | MEINZER ET AL. | |
| | Examiner | Art Unit | |
| | Lakshmi S. Channavajjala | 1615 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
 - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
 - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 06 September 2005.
- 2a) This action is FINAL. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 12-26 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 12-26 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ . |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____ . | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| | 6) <input type="checkbox"/> Other: _____ . |

DETAILED ACTION

Receipt of amendment and response dated 9-6-05 is acknowledged.

Claims 1-11 have been canceled and new claims 12-26 have been added.

Response to Arguments

Applicant's arguments with respect to claim 1-11 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 103

Claims 12-26 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 5,342,625 to Hauer et al (Hauer).

Hauer teaches cyclosporin comprising pharmaceutical compositions in the form of microemulsion pre-concentrates and that are filled in hard gelatin capsules (abstract, examples, col. 29, lines 11-14). Examples 1, 4, 5 in col. 26-29 are directed cyclosporin formulation, which include surfactant Labrafil M 1944 CS and Labrafil M 2130 CS (col. 11), both of which are described in the instant specification as reaction products of hydrogenated or natural vegetable oil ad ethylene glycol. Thus, Hauer teaches the claimed surfactant. Hauer also teaches composition comprising propylene glycol and ethanol that read on the claimed lower alkanols (col. 18, last paragraph to col. 19, 1st paragraph). The pre-concentrate compositions of Hauer are free of water and form spontaneous emulsions (col. 5, lines 57 through col. 6, lines 35) and hence meet the claims 22, 23 and 26. Hauer teaches various amounts of cyclosporin in the examples that is within the claimed ranges (claim 16). Not all of the compositions of Hauer contain additional oils and the claimed lower alkanols. The reference also fails to

specifically exemplify a combination of the claimed surfactants and lower alkanols. However, Hauer teaches employing suitable hydrophilic, lipophilic surfactants, lower alkanols etc., in cyclosporin pre-concentrates so as to achieve a stable microemulsion upon contact with water or administration (col. 5-6). Therefore, employing a combination of the claimed surfactants and lower alkanols and further optimizing the amounts of surfactants, solvents such as propylene glycol, and ethanol would have been obvious for one of an ordinary skill in the art at the time of the instant invention because Hauer describes the claimed surfactants and lower alkanols for their ability to form microemulsion pre-concentrate that impart stable microemulsion upon administration. While Hauer does describe oils, the examples of Hauer do not necessarily contain oils and further instant specification does not define what "substantially free of oils" stands or the upper limit that meets the limitation. Therefore, Hauer still teaches compositions that are substantially free of oils, as claimed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S. Channavajjala whose telephone number is 571-272-0591. The examiner can normally be reached on 9.00 AM -6.30 PM

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571-272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Lakshmi S Channavajjala
Examiner
Art Unit 1615

May 1, 2006